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AWARD NUMBER: W81XWH-12-1-0619

TITLE: Building a Family Systems Model to Promote Adherence to PTSD Treatment

PRINCIPAL INVESTIGATOR: Laura A. Meis, PhD

RECIPIENT: University of Minnesota
Minneapolis, MN 55455-2070

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University of Minnesota

Minneapolis, MN 55455-2070

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14. ABSTRACT
Despite the success of evidence-based psychotherapies (EBTs) for PTSD, only half of patients recover, and 1 in 5 will drop out of treatment all together. One central and underutilized resource in keeping Veterans' in treatment and helping them to gain the most from these treatments is Veterans' families, yet evidence-based strategies for how to best utilize families in treatment have yet to be established. We will survey approximately 378 Veterans and 185 of their significant others before and after participation an EBT for PTSD across three VAs (Minneapolis, Palo Alto, and Phoenix). Data collection for these surveys is ongoing. We will then conduct in-depth interviews with Veterans who attended an EBT yet still suffer with PTSD, their significant others, and their providers, to identify how to help Veterans get the most out of treatment. Findings will provide the evidence-base for when, how, and why family involvement can improve adherence to EBTs for PTSD and treatment outcomes. By studying Veterans and their families as they participate in EBTs for PTSD, we will develop a comprehensive and family-focused understanding of why some service members do not finish treatment and why those who do sometimes fail to fully recover. From these findings, we will develop guidelines for providers, outlining how to involve the families in EBTs for PTSD, and an initial protocol for a family-centered intervention to improve adherence to EBTs for PTSD.

15. SUBJECT TERMS
PTSD, couples, family, psychotherapy

16. SECURITY CLASSIFICATION OF:	17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

Evidence-based psychotherapies (EBTs) for posttraumatic stress disorder (PTSD) result in clinically significant symptom relief for many patients and are recommended as first-line treatments by the VA/DOD Clinical Practice Guideline. Despite the success of these interventions, only half of patients receiving them can be expected to recover, and 1 in 5 will drop out of treatment all together. One central and underutilized resource for maximizing treatment gains is family. PTSD has dramatic negative impacts on social and family relationships, and distress in these relationships predicts negative treatment outcomes. Veterans express strong interest in family-involved PTSD care and multiple organizations, including the VA and DoD, recommend prioritizing family involvement in the treatment of PTSD. Our long term objective is to build evidence-based strategies for how to involve families in EBTs for PTSD to improve treatment outcomes. In order to build these strategies, we must first observe service members and their families as they naturally participate in EBTs as delivered in real-world settings to identify when and how to intervene. The goal of this project is to develop a family-systems model for understanding adherence to EBTs for PTSD and to identify preliminary strategies for family involvement to improve treatment adherence and outcomes.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

PTSD, evidence based psychotherapy, family, psychotherapy adherence

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

The major goals of the project include, 1) To determine the influence of family on treatment adherence among service members referred to EBTs for PTSD, 2) To evaluate a family-systems model of mechanisms of treatment adherence, 3) To obtain an in-depth understanding of the experiences of patients who adhere less to treatment through qualitative, open-ended interviews.

This report covers the first year of the project from 9/30/12 through 9/29/13. Below is a list of milestones and planned periods of completion for each milestone (in study months: "Mo.") and our progress towards those goals, as of this time.

Milestone 1: Obtain required approvals; Planned period of completion: Mo. 1-6: Status: Complete

Milestone 2: Complete Study Start Up Activities; Planned period of completion: Mo. 1-9: Status: Complete

Milestone 3: Complete Time 1 Survey Data Collection for Objective 1 and 2; Planned period of completion: Mo. 10-23

Tasks scheduled during this reporting period: Begin Time 1 recruitment, begin monitoring response rates; Status: Complete

Milestone 4: Complete Qualitative Interview Data Collection for Objective 3; Planned period of completion: Mo. 5-20

Tasks during this reporting period: Finalize draft of qualitative interview guide; Status: Complete

Milestone 5: Complete Time 2 Survey Data Collection for Objective 1 and 2; Planned period of completion: Mo. 7-26

Tasks during this reporting period: Prepare, design, and test scannable Time 2 surveys; Status: Complete

Milestone 6: Create Survey Data Set for Objective 1 and 2; Planned period of completion: Mo. 10-27

Tasks during this reporting period: Begin entering survey data as obtained; Status: Complete

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

The first year of the grant was largely devoted to start up activities. The specific objectives of this period are outlined above in the Milestones review. Each of the study Milestones and Tasks which were scheduled for completion during the period of this report were completed as scheduled. Globally, we have obtained required approvals, completed study start up activities, and begun recruitment of eligible Veterans and their SOs for Time 1 surveys. We are monitoring response rates, developing the qualitative interview guide, preparing, designing, and testing scannable Time 2 surveys, entering and cleaning survey data as obtained, and writing computer syntax to score all measures. Time 1 data collection (mailed surveys) is ongoing and we are preparing for the beginning of Time 2 data collection and qualitative interviews.

Data collection is ongoing. Consequently there are no significant results or key outcomes to report on at this time.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."
Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Over the next year we will begin collecting mailed surveys at Time 2, begin collecting qualitative interview data, and continue to collect Time 1 mailed survey data. We will also process data as it is received, including scanning surveys, transcribing qualitative interviews, and we will begin developing our coding scheme for qualitative interviews.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Data collection is ongoing. Nothing to Report.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Data collection is ongoing. Nothing to Report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Data collection is ongoing. Nothing to Report.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Data collection is ongoing. Nothing to Report.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency

Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

The study PI (Meis) was on extended medical leave from February 2013 through June 2013. A local co-investigator (Spoont) served as acting PI during Dr. Meis' absence. The study progressed in Dr. Meis' absence. However, finalizing survey materials and procedures were delayed awaiting her return. As a result, data collection began in month 12, rather than month 10 as originally proposed.

Additionally, we have been collecting data for a small pilot project using similar procedures across the sites employed in the current award (Minneapolis, Palo Alto, and Phoenix VAs). In this pilot project, the rates of referrals for study recruitment are lower than expected at the Palo Alto VA/Stanford University. As a result, we have submitted a request for a protocol change which is under review to add a site (the Charleston Research Institute; Charleston VA Health Care System) to ensure the success of recruitment efforts and our ability to collect the data within the timeline of the project. Based the volume of patients who typically attend this clinic, this will add an average of 30 referrals for recruitment per month (ranging from 16 to 64 per month). This will easily cover and likely exceed the necessary number of referrals needed to reach our recruitment goals on time for the study. This solution will address potential deficits in referrals from the Palo Alto VA/Stanford University and assist in catching up with recruitment as we are two months behind.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to Report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals.

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Data collection is ongoing. Nothing to Report.

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Data collection is ongoing. Nothing to Report.

  presentation produced a manuscript.

Data collection is ongoing. Nothing to Report.

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Data collection is ongoing. Nothing to Report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Data collection is ongoing. Nothing to Report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Not applicable.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product,

scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *biospecimen collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Data collection is ongoing. Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

Example:

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award).*

Name: Laura Meis
Project Role: Principal Investigator
Nearest person month worked: 3 months (30% effort over 8 months)
Contribution to Project: Laura Meis has preformed oversight over all study activities as PI
Funding Support: DoD

Name: Afsoon Eftekhari
Project Role: Site Investigator (Palo Alto site)
Nearest person month worked: 1 month
Contribution to Project: Dr. Eftekhari has managed project activities at Palo Alto site as well as provided input and expertise on study items such as qualitative interviews, family involvement, site specific information, PTSD, EBT's etc.
Funding Support: DoD

Name: Karen Kattar
Project Role: Site Investigator (Phoenix site)
Nearest person month worked: 1 months
Contribution to Project: Dr. Kattar has managed project activities at Phoenix site as well as provided input and expertise on study items such as qualitative interviews, family involvement, site specific information, PTSD, EBT's etc.
Funding Support: DoD

Name: Rebecca Swain
Project Role: Research Assistant (Phoenix site)
Nearest person month worked: 4
Contribution to Project: Ms. Swain coordinated study activities at the Phoenix site and performed study tasks such as site IRB submissions, data pulls, data entry, data verification, support person nomination/recruitment, management of databases, etc.
Funding Support: DoD

Name: Christine Herb
Project Role: Research Assistant (Phoenix site)
Nearest person month worked: 1
Contribution to Project: Ms. Herb assisted with study activities at the Phoenix site and performed administrative and study tasks, such as site IRB submissions, data pulls and data entry.
Funding Support: DoD

Name: Tina Velasquez
Project Role: Project Coordinator
Nearest person month worked: 8 (start date: 2/11/2013)
Contribution to Project: Ms. Velasquez has managed and coordinated project activities across all sites and has performed such tasks liaison between staff at all sites and with respective companies, study administrative tasks, recruitment, project management, IRB, database management and design, data entry and verification, transcription, etc.
Funding Support: DoD

Name: Melissa Polusny
Project Role: Co-Investigator (MN site)
Nearest person month worked: 1 month
Contribution to Project: Dr. Polusny provided expertise in longitudinal survey methods and optimizing response rates. She has also supported the implementation of provider session notes templates that will gather patients' homework compliance at the Minneapolis VAHCS.
Funding Support: DoD

Name: Christopher Erbes
Project Role: Co-Investigator (MN site)
Nearest person month worked: 1 month
Contribution to Project: Dr. Erbes has overseen the implementation of the project within the Minneapolis VA. Dr. Erbes has provided input and expertise on study items such as qualitative interviews, family involvement, site specific information, PTSD, EBT's etc.
Funding Support: DoD

Name: Michele Spoont
Project Role: Co-Investigator (MN site)
Nearest person month worked: 2 months
Contribution to Project: Dr. Spoont provided expertise in treatment adherence for veterans with PTSD, survey methodology, and qualitative methods. She also served as acting PI during the period of time that Dr. Meis was on medical leave.
Funding Support: DoD

Name: Shelley MacDermid-Wadsworth
Project Role: Consultant (external)
Nearest person month worked: .10
Contribution to Project: Dr. MacDermid-Wadsworth has provided her input and expertise involving military families and qualitative methods with families.
Funding Support:

Name: Josef Ruzek
Project Role: Consultant (external)
Nearest person month worked: .10
Contribution to Project: Dr. Ruzek has provided his input and expertise on various subjects involving PTSD, VA policy, family involvement with PTSD therapy and national efforts to implement and disseminate EBT's for PTSD
Funding Support: DoD

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.
Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name: Minneapolis VA Health Care System
Location of Organization: Minneapolis, MN
Partner's contribution to the project (identify one or more)

- *Study activities take place at the Minneapolis VA and Minneapolis investigators are located at the Minneapolis VA*
- *Facilities (e.g., project staff use the partner's facilities for project activities)*

Organization Name: Phoenix VA
Location of Organization: Phoenix, AZ
Partner's contribution to the project (identify one or more)

- *Study activities take place at the Phoenix VA and Phoenix investigators are located at the Phoenix VA*
- *Facilities (e.g., project staff use the partner's facilities for project activities)*

Organization Name: Palo Alto VA
Location of Organization: Palo Alto, AZ
Partner's contribution to the project (identify one or more)

- *Study activities take place at the Palo Alto VA and Palo Alto investigators are located at the Palo Alto VA*
- *Facilities (e.g., project staff use the partner's facilities for project activities)*

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

9. APPENDICES:

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

None.